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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,933	03/31/2004	Koichiro Kawano	03180.0361	4910
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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER TURNER, SONJ LUCAS	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/812,933	Applicant(s) KAWANO ET AL.	
	Examiner Sonji Turner	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☒ Claim(s) 2,5 and 9-11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/31/2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/31/2004 & 6/23/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "11" has been used to designate both "thin-film heater" at pages 11, 12, 13, 15, and 16 of the specification and "thin-film vibrator" on fig. 6. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: reference character 5 in figs. 4, 6, 7, and 10. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objections to the drawings will not be held in abeyance.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The titles similar to the following

are suggested: “Bilayer Lipid Membrane Forming and Sample-Solution Measuring Device” or “Sample-Solution Measuring Device with Bilayer Lipid Membrane Forming Capability.”

3. The disclosure is objected to because of the following informalities: at page 2, line 26; page 3, lines 11 and 23; page 4, lines 8 and 20; delete “,” between “and” and “e).” Appropriate correction is required.

4. Additionally, portions of the specification appear to be a literal translation into English from a foreign document and are replete with usage, grammatical, and idiomatic errors.

Examples include but are not limited to those found on page 2, line 13; page 7, lines 10-15; page 8 lines 17-18 and 26; and page 9 lines 1-6, etc. A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification must not contain new matter and must be accompanied by a statement that it contains no new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) must also be supplied.

Claim Objections

5. Claims 2, 5, 9, 10, and 11 are objected to because of the following informalities: The phrase “or more” is used in each of the previously mentioned claims at lines 19, 16, 3, 7, and 12,

respectively. It is not clear to what the applicant is referring. For the purpose of examination “or more” is taken to mean higher than a melting temperature of the lipid. Appropriate corrections are required. See below at Claim rejection - 35 U.S.C. 112.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 5, 9, 10, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The term “or more” in the previously mentioned claims at lines 19, 16, 3, 7, and 12, respectively, is a relative term which renders the claim indefinite. The term “or more” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For example in claim 2, one can take “or more” to mean 1) the temperature of the cleaning fluid upon arrival at the substrate film is equal to, or the same as, the melting temperature of the lipid or a temperature higher than the melting point of the lipid; or 2) the temperature of the cleaning fluid upon arrival at the substrate film is equal to, or the same as, the melting temperature of the lipid or “some element, not actually disclosed,” thereby rendering the scope of the claims unascertainable.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible

harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney, or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 7, and 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, and 9 of copending Application No. 10/952,179 (Kinpara '179; US Pub. 2005/0214163) in view of Ikematsu '342 (U.S. Patent 5,378,342).

Claim 1 of the copending application Kinpara '179 recites a device for forming a lipid membrane including a first solution container, a second solution container, a partition wall with a hole, a mechanism which applies lipid the hole, and a mechanism which provides physical stimulus. The Kinpara '179 application does claim the intended usage of a measuring device for detecting dissolved substances in a sample and reference solution of the device as claimed in the instant application. (The instant claim recites that the device detects dissolved substances in the solutions by measuring a potential difference between the solutions and discloses an embodiment wherein a potential difference between the sample and reference solution is measured [0031].) However, Ikematsu '342 does teach a similar device wherein a potential difference is measured

(col. 1, lines 49, 61; col. 2, line 5; col. 3, line 9-36). It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the device of Kinpara '179 with the intended use of Ikematsu '342 in that such usage would have been obvious to one of ordinary skill given that both devices are equivalent lipid membrane devices and one of ordinary skill would have the reasonable expectation that each would function equally well as sample solution measuring devices.

The first solution container corresponds Kinpara '179 and broadly encompasses the sample solution container of instant claim 1, the second solution container of Kinpara '179 corresponds to and broadly encompasses the second reference container of instant claim 1, the partition wall and hole corresponds to and encompasses the substrate film and hole of the instant claim, a mechanism which applies a lipid corresponds to and encompasses the mechanism for ejecting lipid, and a mechanism which provides stimulus corresponds to and encompasses cleaning fluid ejecting mechanism of the instant claim 1.

This is a provisional obviousness-type double patenting rejection.

10. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned copending applications, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that

the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 12, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Ikematsu '342. Ikematsu '342 teaches a sample-solution measuring device that detects dissolved substances in a sample solution and measures a potential difference between the sample solution and a reference solution. The device has a sample solution container; a reference solution container; a substrate thin film located between the sample solution container and the reference solution container that has a hole where a bilayer lipid membrane is formed and the sample solution and the reference solution are in contact with each other. The device has a mechanism to form the bilayer lipid membrane with ejection of a lipid solution and a mechanism that ejects a cleaning fluid to the substrate thin film (abstract; figs. 1-4 and 6; col. 3, lines 10-45; col. 4, lines 2-44; col. 5, lines 31-50; col. 8, lines 5-35). Regarding claims 12 and 13, the mechanism that stirs any of the sample and reference solutions with a stirrer is shown in figs. 2 and 6.

13. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Yoshio et al. (Development of an Eco-Sensor for the Continuous Monitoring of Environmental Volatile Organic Chlorinated Compounds). The device disclosed in Yoshio et al. has a sample solution container; a reference solution container; and a substrate thin film located between the sample solution container and the reference solution container that has a hole where a bilayer lipid membrane is formed. The sample solution and the reference solution are in contact with each other. The device has a mechanism to form the bilayer lipid membrane with ejection of a lipid solution and a mechanism that ejects a cleaning fluid to the substrate thin film. See 1-Introduction; 2-Materials and Methods; 3-Results and Discussion, 3.0 and 3.2; 4-Summary and Future Tasks; figs. 2, 4, 6, 9, 10, and 12.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ikematsu '342.

The teachings of Ikematsu '342 are stated above and disclose the invention essentially as claimed, except for the water levels. It is well known and common sense to one of ordinary skill in the art that water levels must be lower than the hole in order to effectively eject cleaning fluid to the film substrate in order to prevent interference with cleaning by the solutions. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to lower the level of water and solution in order to prevent interference with the cleaning solution being ejected to the film. Moreover, claim 3 is material worked upon the device and in effect imparts no patentable weight to the device, see MPEP § 2114.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshio et al. With regards to claim 4, Yoshio et al. (article on Development of an Eco-Sensor) discloses the invention essentially as claimed, except not explicitly stating a cleaning nozzle. However, Yoshio et al. does teach a nozzle for delivery and ejection (3-results at page 1788 and discussion 3.2 at page 1790 and 1791). It would have been reasonable to one of ordinary skill in the art that the cleaning mechanism would have been the nozzles and such would eject cleaning fluid as well as solution to the membrane. Thus, it would have been obvious to one of ordinary skill in the art the time of the invention that the nozzle would function as a cleaning nozzle as well in order to provide cleaning solution to the system.

17. Claims 2, 5, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikematsu '342.

Claims 2, 5, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikematsu '342 as applied to claim 1 above, and further in view of Ikematsu '922 (U.S. Patents 6,056,922).

The teachings of Ikematsu '342 are stated above; additionally, Ikematsu '342 has a heat source (col. 3, lines 10-45). However, Ikematsu '342 does not teach a mechanism that heats the hole provided on the substrate film, heats the sample and reference solutions, and heats the solutions with a heater to a melting temperature of the lipid or a higher temperature nor does Ikematsu '342 teach a cleaning fluid at a melting temperature of the lipid or a higher temperature. However, Ikematsu '922 does teach each of these limitations (col. 7, lines 40-55). Each prior art reference relates to devices that form bilayer lipid membranes. Since the heated sample and reference solutions are divided with a substrate film and are in contact with the hole that contains the bilayer lipid membrane, then the solutions are the mechanism which also heats the hole. In addition, Ikematsu '342 teaches a surfactant, or cleaning fluid, in the solution of an embodiment (col. 4, lines 36-40). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to heat the solutions for the devices disclosed in Ikematsu '342 with the mechanism taught in Ikematsu '922 for the purpose of forming the bilayer lipid membrane in the hole of the substrate. One skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success.

18. Claims 6, 7, 8, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikematsu as applied to claims 5 and 9 above, and further in view of Case '847 (U.S. Patent 5,328,847).

The teachings of Ikematsu are disclosed above with claims 5 and 9. Ikematsu does not teach a heating or vibrating mechanism nor are each attached to the substrate film. Case '847 does teach a heating mechanism attached to the substrate (fig. 1; col. 6, lines 59-68). It is known in the art that an electrode connected to a direct current voltage source is capable of producing heat and vibration, as a battery is a type of direct current voltage source capable of both. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the devices taught in Ikematsu with the mechanism taught in Case '847 for the purpose of forming the bilayer lipid membrane in the hole of the substrate. One skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure and is listed on PTO-892 (Notice of References Cited). The references are considered to be of interest, as the references relate to the art of bilayer lipid membranes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonji Turner whose telephone number is 571-272-1203. The examiner can normally be reached on Monday - Friday, 10:00 am – 2:00 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Duane Smith can be reached on 571-272-1166. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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1/22/2008

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PRIMARY EXAMINER

2-4-08